EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to sugar beet fibre and increasing faecal bulk pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to sugar beet fibre and increasing faecal bulk pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Nordic Sugar A/S, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Denmark, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim based on newly developed scientific evidence related to sugar beet fibre and "increasing faecal bulk". The food constituent that is the subject of the health claim is sugar beet fibre. The Panel considers that sugar beet fibre is sufficiently characterised in relation to the claimed effect. The claimed effect is "increasing faecal bulk". Increasing faecal bulk may be a beneficial physiological effect. The applicant provided four human and three animal studies. The Panel considers that no conclusions can be drawn from two human studies for the scientific substantiation of the claim. The other two human studies showed an effect of the consumption of sugar beet fibre on increasing faecal bulk. The evidence obtained from three animal studies supports the evidence from human studies. The mechanism by which sugar beet fibre exerts the claimed effect is established. In weighing the evidence the Panel took into account that two human intervention studies showed that consumption of sugar beet fibre increases faecal bulk, that the evidence provided by three animal studies supports that effect, and that the mechanisms by which sugar beet fibre exerts the claimed effect are established. The Panel concludes that a cause and effect relationship has been established between the consumption of sugar beet fibre and increasing faecal bulk. The following wording reflects the scientific evidence: "Sugar beet fibre increases faecal bulk". In order to bear the claim a food should be at least "high in fibre" as per the Annex to Regulation (EC) No 1924/2006. The target population is the general population.

KEY WORDS

Sugar beet fibre, faecal bulk, health claims

[1] On request from the Competent Authority of Denmark following an application by Nordic Sugar A/S, Question No EFSA-Q-2011-00972, adopted on 23 November 2011.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen for the preparatory work on this scientific opinion.

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SUMMARY

Following an application from Nordic Sugar A/S, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Denmark, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to sugar beet fibre and "increasing faecal bulk".

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The food constituent that is the subject of the health claim is sugar beet fibre. The term "sugar beet fibre" includes fibre derived from all plants of the species *Beta vulgaris* L. Sugar beet fibre contains hemicelluloses (22-32 %), pectins (22-29 %), cellulose (19-28 %), protein (5 %), ash (3 %) and moisture (7 %). The presence of both soluble and insoluble polysaccharides is roughly in a 2:1 ratio. This opinion applies to sugar beet fibre naturally present in foods and to those forms added to foods. The Panel considers that the food constituent, sugar beet fibre, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

The claimed effect is "increasing faecal bulk". The target population proposed by the applicant is people who want to improve or maintain a normal bowel function. The Panel considers that increasing faecal bulk may be a beneficial physiological effect.

The applicant identified four human intervention studies and three animal studies as pertinent to the health claim. The Panel considers that no conclusion can be drawn from two human studies for the scientific substantiation of the claim because faecal bulk was not measured. The other two human intervention studies showed an effect of the consumption of sugar beet fibre on increasing faecal bulk. The Panel notes that the evidence obtained from three provided animal studies supports the evidence derived from human studies on the effect of sugar beet fibre on faecal bulk.

The mechanisms by which components of sugar beet fibre exert the claimed effect have been established. The insoluble components of fibre increase faecal bulk by absorbing water in the large intestine. The soluble components are fermented by bacteria in the large intestine leading to an increase in bacterial mass.

In weighing the evidence the Panel took into account that two human intervention studies showed that consumption of sugar beet fibre increases faecal bulk, that the evidence provided by three animal studies supports that effect, and that the mechanisms by which sugar beet fibre exerts the claimed effect are established.

The Panel concludes that a cause and effect relationship has been established between the consumption of sugar beet fibre and increasing faecal bulk.

The Panel considers that the following wording reflects the scientific evidence: "Sugar beet fibre increases faecal bulk".

The Panel considers that in order to bear the claim a food should be at least "high in fibre" as per the Annex to Regulation (EC) No 1924/2006. The target population is the general population.

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 1924/2006[4] harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health), which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA:

- The application was received on 01/09/2011.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- The scientific evaluation procedure started on 20/09/2011.
- During the meeting on 23/11/2011, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to sugar beet fibre and increasing faecal bulk.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to sugar beet fibre and "increasing faecal bulk".

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of sugar beet fibre, a positive assessment of its safety, nor a decision on whether sugar beet fibre is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Nordic Sugar A/S, Langebrogade 1, PO Box 2100, 1014 Copenhagen K, Denmark.

Food/constituent as stated by the applicant

According to the applicant, the food constituent for which the claim is made is sugar beet fibre.

Health relationship as claimed by the applicant

According to the applicant, sugar beet fibre increases faecal bulk.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Sugar beet fibre increases faecal bulk".

Specific conditions of use as proposed by the applicant

According to the applicant, the pattern of consumption is over 7 grams per day. The proposed target population is people who want to improve or maintain a normal bowel function.

ASSESSMENT

1. CHARACTERISATION OF THE FOOD/CONSTITUENT

The food constituent that is the subject of the health claim is sugar beet fibre.

The term "sugar beet fibre" includes fibre derived from all plants of the species *Beta vulgaris* L. Sugar beet fibre contains hemicelluloses (22-32 %), pectins (22-29 %), cellulose (19-28 %), protein (5 %), ash (3 %) and moisture (7 %). The presence of both soluble and insoluble polysaccharides is roughly in a 2:1 ratio (Thibault et al., 2001).

The applicant markets sugar beet fibre under the brand name Fibrex® in the form of powder/grains with different particle sizes, coarse (not milled) form, and coarse pulp grains pressed into flakes. The manufacturing process is described and stability data are provided.

This opinion applies to sugar beet fibre naturally present in foods and to those forms added to foods.

The Panel considers that the food constituent, sugar beet fibre, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

2. RELEVANCE OF THE CLAIMED EFFECT TO HUMAN HEALTH

The claimed effect is "increasing faecal bulk". The target population proposed by the applicant is people who want to improve or maintain a normal bowel function.

The Panel considers that increasing faecal bulk may be a beneficial physiological effect.

3. SCIENTIFIC SUBSTANTIATION OF THE CLAIMED EFFECT

The applicant searched the databases MEDLINE, CAB Abstracts, Food Science & Technology Abstracts, and Foodline:Science fibre for beet fiber OR beet fibre AND intestinal OR intestine OR constipation OR bowel OR gastrointestinal OR health OR healthy OR faeces OR faecal OR humans NOT pig OR rat OR mice. Internet was searched with Google for "sugar beet fibre" OR "sugar beet fibre" AND "bowel function" OR" fecal bulk" OR "stool weight" OR "transit time". The applicant identified four human studies and three animal studies as pertinent to the health claim.

One open label, one-arm, uncontrolled study (Giacosa et al.,1990) investigated the effects of sugar beet fibre on stool frequency and consistency in 27 subjects with chronic constipation. One randomised cross-over study (Langkilde et al., 1993) assessed the effects of sugar beet fibre on cholesterol, bile acid and total (dry and wet weight) ileostomy excretion in nine ileostomy patients. Faecal bulk was not measured in any of these studies.

The Panel considers that no conclusion can be drawn from these two studies for the scientific substantiation of the health claim.

In a randomised, cross-over study, Lampe et al. (1993) evaluated the effect of supplemental sugar beet and wheat fibre on faecal weight and intestinal transit time in 20 healthy men (20-40 years). Subjects consumed 20 g/d of either sugar beet fibre or wheat fibre for 30 days each after a 20-day run-in period during which all subjects consumed a self-selected diet providing about 22 g/day of dietary fibre. Subjects were asked to maintain their usual (self-selected) diet for the entire duration of the study. The Panel notes that this study does not have a washout period. Fibre supplements were consumed with meals. Faeces were collected from day 11 to day 20 of the run-in and each feeding period. A total of 17 men completed the study and entered data analysis. It is reported that the effect of treatment was assessed by analysis of variance (ANOVA) for cross-over designs taking into account the three study periods (run-in, sugar beet fibre and wheat fibre) and their sequence. However, the Panel notes that the statistical analyses performed are not fully described. Wet and dry faecal weights during consumption of sugar beet fibre were significantly higher than during the run-in (self-selected diet) period (mean±SEM; wet faecal weight: 276±10 g/d *vs.* 198±10 g/d, $p<0.0001$; dry faecal weight: 67±2 g/d *vs.* 49±2 g/d, $p<0.0001$, respectively). No significant differences were reported in relation to wet faecal weight between the sugar beet and wheat fibres, whereas dry faecal weight was significantly higher in the sugar beet fibre period than in the wheat fibre period (67±2 g/d *vs.* 57±2 g/d, $p<0.001$). The Panel notes that wheat fibre has an established role in increasing faecal bulk in humans (EFSA Panel on Dietetic Products Nutrition and Allergies, 2010). The Panel considers that this study shows an effect of sugar beet fibre on increasing faecal bulk.

In a randomised study with Latin-square design (3x3), nine healthy men (mean age 21.5 years) consumed either a control diet (22 g/d dietary fibre) or the same control diet supplemented with 50 g/d of either sugar beet fibre or inulin from chicory for 28 days each (Castiglia-Delavaud et al., 1998). Each experimental period comprised 2 days (days 1 and 2) with the control diet, 14 days (days 3–16) with a progressive adaptation to the intervention up to a maximum of 50 g/d; and 12 days (days 17-28) with a constant maximum intake of fibre. Diets were partially controlled (lunch and dinner were provided by the nutrition laboratory). Primary outcomes of the study were metabolisable energy and net metabolisable energy of the diets. Secondary outcomes were energy expenditure, faecal weight, frequency of defecations and faecal bacterial mass. The Panel notes that faecal weight was a secondary endpoint of the study. Comparisons between experimental diets were performed by ANOVA using the general linear models procedure according to a Latin-square design with three repetitions. Wet and dry faecal weights during consumption of sugar beet fibre were significantly higher than during the control diet (mean±SEM; wet faecal weight: 202±16 g/d *vs.* 129±16 g/d, $p<0.05$; dry faecal weight: 37.6±2.3 g/d *vs.* 27.7±2.3 g/d, $p<0.05$, respectively). Also mean faecal bacterial weight (presented as dry matter) was significantly higher in sugar beet fibre group in comparison to the control diet (20.3±1.2 g/d *vs.* 13.0±1.2 g/d, $p<0.01$). No significant differences were reported in relation to wet or dry faecal weights between the sugar beet and inulin fibres. The Panel considers that this study shows an effect of sugar beet fibre on increasing faecal bulk.

The applicant also provided three animal studies on the effects of sugar beet fibre on faecal bulk. In two of these studies, addition of sugar beet fibre (100 g/kg feed) to the usual diet (Nyman and Asp, 1982) or to a fibre-free diet (Johnson et al. 1990) induced a significant increase in faecal wet and dry weights in rats. In the third study (Klopfenstein,1990), coarse and fine sugar beet fibre fed at different doses (5, 7.5, and 10 % of the diet) induced a dose-response increase in wet and dry faecal weight which was apparently independent of particle size. The Panel considers that the evidence provided by these three animal studies supports an effect of sugar beet fibre on increasing faecal bulk.

The mechanisms by which components of sugar beet fibre exert the claimed effect have been established. The insoluble components of fibre increase faecal bulk by absorbing water in the large intestine. The soluble components are fermented by bacteria in the large intestine leading to an increase in bacterial mass (Stephen and Cummings, 1980; Chen et al., 1998).

In weighing the evidence the Panel took into account that two human intervention studies showed that consumption of sugar beet fibre increases faecal bulk, that the evidence provided by three animal studies supports that effect, and that the mechanisms by which sugar beet fibre exerts the claimed effect are established.

The Panel concludes that a cause and effect relationship has been established between the consumption of sugar beet fibre and increasing faecal bulk.

4. PANEL'S COMMENTS ON THE PROPOSED WORDING

The Panel considers that the following wording reflects the scientific evidence: "Sugar beet fibre increases faecal bulk".

5. CONDITIONS AND POSSIBLE RESTRICTIONS OF USE

The Panel considers that in order to bear the claim a food should be at least "high in fibre" as per the Annex to Regulation (EC) No 1924/2006. The target population is the general population.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, sugar beet fibre, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.
- The claimed effect is "increasing faecal bulk". The proposed target population for the health claim is people who want to improve or maintain a normal bowel function. Increasing faecal bulk may be a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of sugar beet fibre and increasing faecal bulk.
- The following wording reflects the scientific evidence: "Sugar beet fibre increases faecal bulk".
- In order to bear the claim a food should be at least "high in fibre" as per the Annex to Regulation (EC) No 1924/2006. The target population is the general population.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on sugar beet fibre and "increasing faecal bulk" pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0312_DK). September 2011. Submitted by Nordic Sugar A/S.

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